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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,349	09/01/2004	Motohiro Ohta	09859/0201805-US0	1041
7278	7590	09/07/2007		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER HAGOPIAN, CASEY SHEA	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,349

Applicant(s)

OHTA ET AL.

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19-27, 29, 30 and 77-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19-27, 29, 30 and 77-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 6/14/2007.

Claims 1-16, 18, 28 and 31-76 have been cancelled. Claims 77-79 have been newly added. Claims 17, 29 and 30 have been amended. Thus, claims 17, 19-27, 29, 30 and 77-79 are currently pending.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 12/15/2006:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** There is no teaching of "the ratio of D-mannitol" or "the ratio of the disintegrator". The specification teaches compounding ratios of D-

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mannitol and a disintegrator (page 14), thus it is suggested that applicant employ the same language into the claims.

Response to Amendments/Arguments

The cancellation of claims 1, 3-7, 9, 10, 14, 15, 31, 33-37, 39, 40, 45, 47, 49-53, 55, 56, 61, 63-67, 69, 70 and 75 renders the rejection under 35 USC 102 in view of Yoshinari moot. Thus, the rejection of *those* claims has been withdrawn.

The cancellation of claims 1, 3, 7-11, 13-16, 31, 33, 37-41, 43-49, 53-57, 59-63, 67-71 and 73-76 renders the rejection under 35 USC 102 in view of Ohta moot. Thus, the rejection of *those* claims has been withdrawn.

The cancellation of claim 3 renders the rejection under 35 USC 112, 1st paragraph (i.e., new matter) moot. Thus, the rejection of said claim has been withdrawn.

The cancellation of claims 12-14, 28, 40-44, 58-60 and 72-74 renders the rejection under 35 USC 112, 1st paragraph (i.e., new matter) moot. Thus, the rejection of *those* claims has been withdrawn.

The amendments to claims 29 and 30 still appear to include new matter. The claims recite the limitations, "wherein the ratio...". Said limitation is not

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sufficiently supported by the specification. It is suggested that applicant use the language from the specification, which is, "wherein the compounding ratio" (see page 14). Thus, the new matter rejection of claims 29 and 30 under 35 USC 112, 1st paragraph is maintained. The amendment also introduces a 112, 2nd paragraph issue (see *New Rejections*).

The cancellation of claim 3 renders the rejection under 35 USC 112, 2nd paragraph moot. Thus, the rejection of said claim has been withdrawn.

The amendments/arguments render the rejection of claims 17, 19-23, 25 and 26 under 35 USC 103 in view of Yoshinari moot. Thus, said rejection has been withdrawn.

The amendments/arguments render the rejection of claims 17, 19, 23-27, 29 and 30 under 35 USC 103 in view of Ohta moot. Thus, said rejection has been withdrawn.

NEW REJECTIONS

The following rejections are new in light of the amendments submitted 6/14/2007:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 19-27, 29, 30 and 77-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** Claim 17 recites the limitation, "the ratio of the fine granules". There is no teaching of "the ratio of the fine granules" in the specification. The specification teaches compounding ratios of the fine granules (page 14), thus it is suggested that applicant employ the same language into the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 20, 21, 23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech et al. (USPN 5,681,577).

Lech teaches a method of making a cold/sinus preparation (abstract). Said method comprising wet granulation of the active agents and an adsorbent, namely, silicon dioxide (abstract; col. 3, lines 61-63; Examples). Lech teaches the adsorbent to comprise about 50% to about 85% of the adsorbate composition, which translates to a ratio of actives to adsorbate being approximately about 1:10 to 1:1 (abstract). Example III teaches that the actives and adsorbent make up 25% (i.e., 1.25% + 3.0% + 20.75%) of the total weight of the preparation. Example III also teaches that once the drug adsorbate is created, additional excipients including sweeteners, colorants, flavorings are blended with the drug adsorbate, the particular lubricant, magnesium stearate, is

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then added to the mixture and the subsequently compressed into tablets. The actives taught by Lech are water-soluble as evidenced by the step of dissolving the actives in water prior to the wet granulation step (Examples). Also, a preferred active agent described by Lech is Diphenhydramine HCl (Example III), which has a solubility of 1g/1mL as evidenced by The Merck Index. Lech teaches incorporating particular excipients including disintegrants such as microcrystalline cellulose and other cellulose derivatives in order to aid in the tableting and oral administration processes (col. 4, lines 6-8) as well as mannitol as a tableting agent (claim 18). It is noted that D-mannitol and mannitol are analogous to one another as evidenced by the Handbook of Pharmaceutical Excipients (page 177). It is further noted that mannitol has a specific surface area of 0.60 m²/g and has a particle size distribution between about 60 and 180 microns as evidenced by the Handbook of Pharmaceutical Excipients (Figure 3; page 179).

Lech does not require a disintegrant. Lech, however, provides motivation for including a disintegrant because Lech teaches that a disintegrant aids in the tableting and oral administration processes (col. 4, lines 6-8). A practitioner would have reasonably expected a tablet comprising a drug adsorbate, D-mannitol and a disintegrant for oral administration. Thus, it would have been obvious for one skilled in the art at the time the invention was made to include a disintegrant as suggested by Lech.

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Claims 19 and 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech et al. (USPN 5,681,577) in view of Remington: The Science and Practice of Pharmacy (referred to hereinafter as "Remington").

Lech teaches the elements discussed above including disintegrants such as microcrystalline cellulose and other cellulose derivatives. Lech is silent to the particular disintegrants, crospovidone, low-substituted hydroxypropyl cellulose, croscarmellose sodium and carboxymethylcellulose.

Remington teaches well known disintegrants used in the preparation of tablets including crospovidone and celluloses such as croscarmellose and carboxymethylcellulose (page 1619). Both references teach tablets and conventional tableting methods containing conventional tablet ingredients. It would have been obvious to one skilled in the art at the time the invention was made to substitute one disintegrant for another because they are art-recognized equivalents and said substitution would achieve the predictable result of producing a tablet.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is

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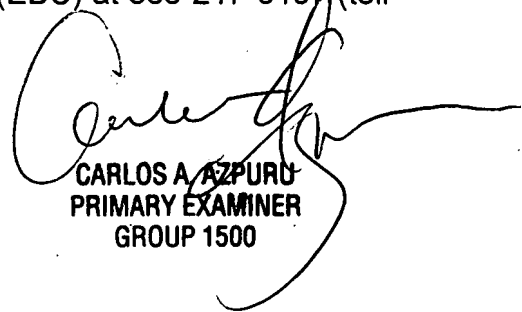
571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Casey Hagopian
Examiner
Art Unit 1615



CARLOS A. AZPURU
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